K101951

Reliance Orthodontic Products, Inc.
Toll Free 1-800-323-4348 · Phone 630-773-4009 · Fax 630-250-7704
1540 West Thorndale Ave. · Itasca, IL · 60143 · U.S.A.

OCT 2 6 2010

Section 5.0 510 (k) Summary

Note: This summary is provided in accordance with 21CFR807.92 (c).

510 (k) Owners Name: Reliance Orthodontic Products, Inc.
Paul Gange, President

Address: 1540 West Thorndale Avenue
Itasca, Il 60143 USA

Phone Number: 630-773-4009
Fax Number: 630-250-7704

Contact Person: Paula Wendland, Regulatory Affairs Manager (Preparer)

Date 510 (k) Summary was Prepared: June 24th, 2009

Medical Device Name:

- Trade name – L.C.R.™
- Common name – Flowable Light Cure Orthodontic Adhesive
- Classification name – Bracket Adhesive Resin and Tooth Conditioner (21CFR872.3750, Product Code DYH, Class II Device)

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCE IS CLAIMED (PREDICATE DEVICE) [807.92(a) (3)]:

- Flowtain™

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5.1 DESCRIPTION OF THE APPLICANTS DEVICE:

L.C.R.™ is a light-cure orthodontic adhesive that is flowable and a highly filled resin in order to provide durability. These properties make it ideal for bonding lingual retainers, creating occlusal buildups and for the retention of a thermo-plastic aligner.
L.C.R is available in push syringe, luer-lok syringe or tips for preferences in dispensing.

5.2 INTENDED USE AND POPULATION:

L.C.R.™ is a flowable, light-cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the bonding of lingual retainers, creation of occlusal buildups and for the retention of thermo-plastic aligners.

5.3 PREDICATE DEVICE:

Reliance Orthodontic Products, Inc. Flowtain™, 510(k) submission (K083051) dated 02/20/2009.

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5.4 TECHNOLOGICAL AND PERFORMANCE CHARACTERISTICS:

Performance Characteristics comparison of L.C.R.™ versus Flowtain™:

Property	LCR™	Flowtain™
Intended Use	**Light Cure adhesive for bonding lingual retainers, creation of occlusal buildups and retention of thermoplastic aligners**	**Light Cure adhesive for bonding lingual retainers, and retention of thermoplastic aligners**
Mechanical / Physical Properties	**Flowable Composite Light Cure**	**Flowable Composite Light Cure**
Storage	**Room Temperature**	**Room Temperature**
Shelf Life	**2 years**	**2 years**
Delivery	**Syringe and Tips**	**Syringe**
Flexural Strength	**Performance consistent with ISO 4049:2009 requirements**	**Performance consistent with ISO 4049:2009 requirements**
Depth of Cure	**Performance consistent with ISO 4049:2009 requirements**	**Performance consistent with ISO 4049:2009 requirements**
Bonding of Lingual Retainers	**Successful bond of wire to tooth withstanding multidirectional force**	**Successful bond of wire to tooth withstanding multidirectional force**
Bonding of Thermoplastic Aligners	**Adhesive created retentive surface for thermoplastic aligner.**	**Adhesive created retentive surface for thermoplastic aligner.**

5.5 Summary:

LCR™ claims substantial equivalence to the product, Flowtain™ (K083051). L.C.R. ™ was tested and compared to Flowtain™ for Flexural Strength and Depth of Cure via ISO 4049:2009(E) test method. Testing resulted in similar performance between the two adhesives for both Flexural Strength and Depth of Cure.

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In addition, five replicates of a Compressive Strength Test were conducted for occlusal build-up suitability. This testing was conducted to show the intended use of L.C.R.™ for this procedure was effective. Acceptable results were obtained for Compressive Strength.

For safety, L.C.R.™ has been tested via an Oral Toxicity Study using a 10 Mouse, 7 Day Method (Solid). L.C.R.™ showed no significant evidence of toxicity.

Based on the data comparison between LCR™ and the predicate device, Flowtain™, the intended use testing and oral toxicity study, LCR™ was determined to be safe and effective for its intended use. Testing against the predicate device showed equivalent performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Paula Wendland
Regulatory Affairs Manager
Reliance Orthodontic Products, Incorporated
1540 West Thorndale Avenue
Itasca, Illinois 60143

OCT 2 6 2010

Re: K101951
Trade/Device Name: L.C.R™
Regulation Number: 21 CFR 872.3750
Regulation Name: Bracket Adhesive Resin and Tooth Conditioner
Regulatory Class: II
Product Code: DYH
Dated: October 8, 2010
Received: October 8, 2010

Dear Ms. Wendland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

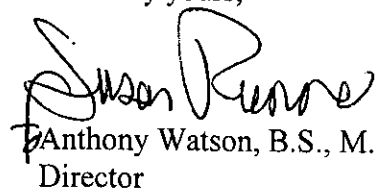
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 6.0 INDICATIONS FOR USE STATEMENT

Indications for Use

OCT 2 6 2010

510 (k) Number (if known): K101951

Device Name: L.C.R.™

Indications for Use:

L.C.R.™ is a flowable, light-cure orthodontic adhesive intended to be used within an orthodontic, dental or pediatric dental office for the bonding of lingual retainers, creation of occlusal buildups and for the retention of thermo-plastic aligners.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K101951